UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

June 30, 2009

DP BARCODE:	**# 364587**
MRID:	**# 475448-01, # 475448-02, # 475448-03**
SUBJECT:	**HeiQ AGS-20**
REG. NO. OR FILE SYMBOL:	**85249-R** 85249-6
DOCUMENT TYPE:	**Product Chemistry Review**
Manufacturing-use [X] **OR**	**End-use Product []**
INGREDIENTS (PC Codes)	**Silver (072501)**
CAS Number:	**7440-22-4**
TEST LAB:	**RCC Ltd, Zwitzerland**
SUBMITTER:	**HeiQ Materials AG, Switzerland**
GUIDELINE:	**OPPTS Test Guidelines 830 Group A and B**
REVIEWER:	**Alex Traska**
ORGANIZATION:	**AD**
APPROVER:	**Karen P. Hicks**
APPROVED DATE:	7/2/09
COMMENT:	**New Product Application**

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MEMORANDUM

Subject: Review for EPA Reg. No. 85249-R

From: Alexander W. Traska, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

AWT 6/30/2009

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

signed for KPH
7/2/09

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell/PM #33 (Denise Fuller)
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: HeiQ Materials AG
Action Code: (540) New Product, Non-Fast-Track
Due out date: 15 August 2009

Formulations from Label

Active Ingredient(s)	% by wt.
Silver metal (Ag)	19.3
Other Ingredients	80.7
Total	100.0

I BACKGROUND

This new product registration, for the subject industrial antimicrobial silver additive, was submitted by the registrant, HeiQ Materials AG, Switzerland.

HeiQ Materials AG has submitted an application for registration of the new manufacturing-use product, **HeiQ AGS-20**. This product is an antimicrobial additive for use in manufacturing, formulating, and fabricating fibers, films, plastics, polymeric materials, cellulose based materials, latex, products, and ceramics. The product is for commercial and industrial use only. The data package included a pre-reaction and post reaction Confidential Statement of Formula (CSF) for the basic formulation (dated September 8, 2008). The product is produced by an integrated formulation system (i.e., the product contains an active ingredient that is not an EPA registered product).

The following documents were submitted and examined in the chemistry review of this submission: registrant's cover letter dated September 8, 2008, proposed Basic CSF (pre and post-reaction) dated September 8, 2008 and draft product label identified HeiQ-RRG-08-1. Also provided was product chemistry data covering OPPTS Test Guideline Series 830 Group A studies under MRID #475448-01 dated September 8, 2008 and MRID #475448-02 dated August 28, 2008 and Group B physical/chemical properties under MRID #475448-03 dated September 15, 2008.

A preliminary chemistry review of this new product registration was made by CSC Systems & Solutions LLC (CSS) and all relevant comments from the June 23, 2009 CSS review were incorporated into this Product Chemistry Review.

II FINDINGS

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient, silver, as shown in the proposed post-reaction Basic CSF, dated September 8, 2008, agreed with the percentage declared on the product label.

2. Standard certified limits were proposed for the active ingredient, silver.

3. The active and inert ingredients utilized in the proposed Basic CSF are cleared for use in this and other pesticide formulations

4. Since the product is produced by an integrated system of manufacture, the registrant provided a pre- and post-reaction Basic CSF. This format or type of formula disclosure format is accepted.

5. The following revisions to the CSF must be made:

- Under Item #10 on the post-reaction CSF, identify silver as the active ingredient and list its CAS registry number as "7440-22-4."

- Under Item #10 on the post-reaction CSF, identify [redacted] as a formulation component.

- Under Item #10 on the post-reaction CSF, identify the CAS registry number for [redacted]

- Under Item #14a and #14b of the post-reaction CSF, identify the upper and lower certified limits for [redacted].

- The CSF was not signed by the approving official as is required

6. The study reports under MRID # 475448-01 and #475448-02 contained data responding to the requirements of OPPTS Test Guidelines 830 Group A. The data provided are acceptable with the exception of OPPTS 830.1750 (Certified Limits). To satisfy OPPTS 830.1750 (Certified Limits) requirements, a signed certification statement must be provided, as requested under OPPTS 830.1750(g).

A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID #475448-02 (quantification of silver in five batches of HeiQ AGS-20 and validation of the analytical method). The study was performed in compliance with the Swiss Ordinance relating to GLP. These principles are compatible with GLP regulations specified by regulatory authorities in the U.S. (EPA and FDA).

7. The Group B product chemistry data requirements applicable to manufacturing-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. Testing of the product is currently underway. Accelerated study results (for a 14-day interval) were provided. The concentration of the active ingredient in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year. Storage and disposal information on the product label must be revised if product composition (or packaging) deteriorates over time.

Statements of Good Laboratory Practice (GLP) compliance were provided for five RCC Ltd. studies compiled within the study assigned MRID # 475448-03. The studies were performed in compliance with the Swiss Ordinance relating to GLP. These principles are compatible with GLP regulations specified by regulatory authorities in the U.S. (EPA and FDA).

III CONCLUSIONS

This new product application, which requested the approval to register a new silver based manufacturing-use product under the **HeiQ AGS-20** registration, is accepted with comment.

Registrant is requested to address all issues and deficiencies noted above in the Findings.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]

Note: The product label states that the product may not be used for any applications involving food contact, food packaging, or drinking water.

c. Physical state of product: *Solid (fine powder)*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X]
No []

Note: Standard certified limits were proposed for the active ingredient.
Note: The CSF must be revised to identify the inert component of the product (i.e., [redacted]). The CSF must be revised to identify the upper and lower certified limits for [redacted].

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Silver	19.3	18.3	20.3

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]

Inert ingredient information may be entitled to confidential treatment

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	475448-01 and CSF
830.1600 Description of Materials	A	475448-01
830.1620 Production Process[2]	A	475448-01 and CSF

Data Requirements	Acceptance of Information	MRID No.
830.1650 Formulation Process[3]	NA	
830.1670 Formation of Impurities[4]	A	475448-01
830.1700 Preliminary Analysis[5]	A – Results from the analysis of five batches of the product were provided. Testing was conducted in compliance with GLP.	475448-02
830.1750 Certified Limits[6]	A G – The CSF must be revised to identify the inert component of the product (i.e., [redacted]). The CSF must be revised to identify the upper and lower certified limits for [redacted] G – A signed certification statement must be provided, as requested under OPPTS 830.1750(g).	475448-01 and CSF
830.1800 Analytical Method[7]	A – A copy of a validated atomic absorption spectroscopy (AAS) method was provided.	475448-02
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for manufacturing-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Inert ingredient information may be entitled to confidential treatment

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is brown, based on visual inspection.	475448-03
830.6303 Physical State	A	The product is a fine powder, based on visual inspection.	475448-03
830.6304 Odor	A	The product has a slightly earthy odor.	475448-03
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for manufacturing-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	The product contains no oxidizing or reducing agents.	475448-03
830.6315 Flammability/ Flame Extension	A	The product does not contain combustible liquids.	475448-03
830.6316 Explodability	A	The product is not potentially explosive.	475448-03
830.6317 Storage Stability	G	An accelerated storage stability study was conducted. Samples of the product were stored for 14 days at 54°C in a commercial container (i.e., polyethylene flask with security closure and a white sealing insert). The following parameters were assessed initially and at the 14-day interval: physical appearance (e.g., color, physical state, odor), active ingredient concentration, and container weight. No changes in the physical appearance of the product were noted through the 14-day interval, for samples stored at 54°C. The active ingredient concentration decreased by 1.17% at the 14-day interval, for samples stored at 54°C. The container lost 0.13% of its weight during	475448-03

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		storage. CIPAC MT 46.3 was referenced. Testing was conducted in compliance with GLP. A storage stability study is currently underway. Results will be provided to EPA once the study is complete.	
830.6319 Miscibility[1]	NA	The product is a solid.	
830.6320 Corrosion Characteristics	G	An accelerated corrosion characteristics study was conducted. Samples of the product were stored for 14 days at 54°C in a commercial container (i.e., polyethylene flask with security closure and a white sealing insert). The appearance of the container was evaluated initially and at the 14-day interval. At the 14-day interval, the appearance of the container was unaltered. Testing was conducted in compliance with GLP. A corrosion characteristics study is currently underway. Results will be provided to EPA once the study is complete.	475448-03
830.6321 Dielectric Breakdown Voltage	NA	The product is a solid.	
830.7000 pH[2]	A	The mean pH of the product was reported to be 7.2 at 22°C. A 1% solution of the product in water was tested. Two determinations were made. CIPAC MT 75.3 was referenced. Testing was conducted in compliance with GLP.	475448-03
830.7050 UV/Visible Absorption	NA	*[Not required for manufacturing-use products.]*	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7100 Viscosity	NA	The product is a solid.	
830.7200 Melting Point/Melting Range	A	The product did not melt in the temperature range between 25°C to 400°C (using a differential scanning calorimeter). EEC Directive 92/69/EEC Method A.1 and OECD Guideline No. 102 were referenced. Testing was conducted in compliance with GLP.	475448-03
830.7220 Boiling Point/Boiling Range	NA	*[Not required for manufacturing-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The mean tap density of the product was reported to be 0.123 g/mL. Two determinations were made. CIPAC MT 159 was referenced. Testing was conducted in compliance with GLP.	475448-03
830.7370 Dissociation Constants in Water	NA	*[Not required for manufacturing-use products.]* The product contains no acid or base functionality.	475448-03
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for manufacturing-use products.]* The product is an inorganic substance.	475448-03
830.7840/830.7860 Water Solubility	A	The water solubility of the product was reported to be 210.3 mg Ag/L at 20°C, using the flask shaking method. Two determinations each were made after 24, 48, and 72 hours of agitation. EEC Directive 92/69/EEC Method A.6 and OECD Guideline No. 105 were referenced. Testing was conducted in compliance with GLP.	475448-03
830.7950 Vapor Pressure	NA	*[Not required for*	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		manufacturing-use products.]	

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water